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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER

STOCKTON, LAURA

ART UNIT PAPER NUMBER

1626

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|--------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/762,006 | | HOTTKOWITZ, THOMAS | |
| | Examiner | | Art Unit | |
| | Laura L. Stockton, Ph.D. | | 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30,32-35 and 43-45 is/are pending in the application.
- 4a) Of the above claim(s) 16-30,32,34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 33 and 43-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-30, 32-35 and 43-45 are pending in the application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 28, 2003 has been entered.

Election/Restrictions

Applicants' election with traverse of Group XI and the species of compound 372 in Paper No. 9 (filed June 14, 2002) was acknowledged

in the Office Action mailed July 11, 2002 {Paper No. 10}. The requirement was deemed proper and made FINAL.

Subject matter not embraced by elected Group XI and claims 16-30, 32, 34 and 35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15, 33 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over AT 393505 and Eibl et al. {EP 534,445}, each taken alone.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim phosphates and phosphoamines. AT 393505 teaches phosphates and phosphoamines which are structurally similar to the instant claimed compounds (see page 9, lines 22-47 and especially Examples 13 and 14 on page 18). Eibl et al. also teach phosphate esters which are structurally similar to the instant claimed compounds (page 2, lines 25-42 and Example 5 on page 6).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between some of the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of “some” among “many” is *prima facie* obvious. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., cytotoxic activity).

One skilled in the art would thus be motivated to prepare compounds embraced by the prior art to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial products which would have cytotoxic activity and can be used to treat tumors. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicants’ arguments filed August 28, 2003 have been fully considered. Applicants argue that: (1) the random selection of some or a few compounds from a large group is not a *prima facie* case of

obviousness; and (2) an impermissible “obvious to try” rationale is being applied.

All of Applicants’ arguments have been considered but have not been found persuasive. Applicants claim phosphates and phosphoamines. AT 393505 teaches phosphates and phosphoamines which are structurally similar to the instant claimed compounds (see page 9, lines 22-47 and especially Examples 13 and 14 on page 18). Eibl et al. also teach phosphate esters which are structurally similar to the instant claimed compounds (page 2, lines 25-42 and Example 5 on page 6). The specific examples prepared in the prior art references differ from Applicants’ compounds by a methylene group {e.g., $-\text{CH}_2-$ }.

For instance, in comparison of instant claim 1 and Example 14 on page 18 in AT 393505 {applied under 35 U.S.C. § 102(b) in the Office Action mailed July 11, 2002 – Paper No. 10}, the difference is a methylene group. See in instant claim 1 wherein $p+q$ is 13 (p is 8 and q is 5) and Example 14 in AT 393505 wherein $p+q$ is 12 (p is 8 and q is 4). The difference being a pentyl group (the value of the instant q

variable is 5) in the instant claimed invention versus a butyl group in the prior art (the value of the instant q variable is 4). To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). Therefore, the examples in the prior art would lead one skilled in the art to the instant claimed invention.

Further, Applicants argue that the Examiner has applied an “obvious to try standard”. An “obvious to try” standard is deemed impermissible in two situations: 1) where the prior art gives no indication as to which of numerous parameters are critical, or gives no indication as to which of many possible choices is likely to be successful; and 2) where the prior art gives only general guidance with respect to the form of the invention, but not how to achieve it in new areas of technology or in fields of experimentation which are only seemingly promising. In re O’Farrell, 7 U.S.P.Q. 2d 1673, 1681 (Fed. Cir. 1988). Because, AT

393505, for example, disclose Example 14 which differs from the instant claimed compounds by a methylene group (e.g., homology), the instant rejection under 35 U.S.C. § 103 is not based on the improper “obvious to try” standard adopted by the Federal Circuit as set forth in O’Farrell. The rejection of the claims is deemed proper and is therefore maintained.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains subject matter drawn to inventions nonelected with traverse in Paper No. 9. A complete reply, if any, to the final rejection must include cancellation of nonelected subject matter (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

September 26, 2003